The PRESIDING OFFICER. Without objection, it is so ordered.

MORNING BUSINESS

Mr. BROWN. Mr. President, I ask unanimous consent that the Senate proceed to a period for the transaction of morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

DEFENSE AUTHORIZATION

Mrs. CLINTON. Mr. President, from day one, the Bush administration has pursued an aggressive agenda of privatizing essential Government services, even when there has existed overwhelming evidence that doing so would waste money, impair accountability, harm citizens who rely on those services, or jeopardize our Nation's safety and security. The Kennedy-McCaskill amendment on civilian contracting will slow this agenda and bring some much needed common sense to the administration's campaign to outsource essential functions to the private sector.

Among other reforms, the amendment will nullify an edict imposed from outside the Department of Defense that the agency contract out a certain number of jobs regardless of the merits; give Federal employees the same rights to challenge a contracting decision that are now enjoyed by private contractors; and eliminate a wasteful rule that civilian jobs automatically be recompeted at the end of each performance period. I am a strong supporter of the Kennedy-McCaskill amendment, which will serve as an important check on the administration's privatization agenda.

UNSOLVED CIVIL RIGHTS CRIMES

Mr. COBURN. Mr. President, I objected to a unanimous consent request to pass S. 535/H.R. 923, the Emmett Till Unsolved Civil Rights Crime Act. I objected, not because I disagree with the well intended motives of the legislation, but because the authors of the bill refused to work with me to make some commonsense changes.

Let me be clear, I absolutely support the goals of this legislation and believe that those who committed civil rights crimes must be brought to justice, but I believe that we can and must do so in a fiscally responsible manner.

Just last week, the Senate voted to increase the Federal Government's debt limit to $9.815 trillion. It is beyond irresponsible to pass any bill that will add to this debt that will be inherited by our children and grandchildren. Even our best intentions need to be paid for with offsets from lower priorities or wasteful spending.

On February 5, 2007, I sent a letter to my colleagues outlining my intent to object to any legislation authorizing new spending that is not offset by reductions in real spending elsewhere. I strongly believe that Congress should stop borrowing and spending beyond our means. Instead, Congress, like all families, ought to prioritize spending and reduce less important spending when greater priorities arise.

S. 535/H.R. 923 violates two of the principles that I outlined in my February letter. These are: If a bill authorizes new spending, it must be offset by reductions in real spending elsewhere; and if a bill creates or authorizes a new Federal program or activity, it must not duplicate an existing program or activity.

This bill authorizes unpaid for new spending and creates a new government program that duplicates existing government efforts. Both of these concerns could be easily addressed if the sponsors of the bill were interested in securing its passage.

In June of this year, my office contacted the bill's sponsors to suggest possible offsets so that I could give my consent—but there was no desire, at the time, to amend the bill. This was unfortunate because last Congress, when Senator Jim Talent was the lead sponsor, he agreed to include offsets in exchange for my consent, but the compromise language was opposed by an unidentified Senator.

It is also unfortunate because there is no shortage of potential offsets for this bill within the Department of Justice, which would administer the proposed program. The bill authorizes $12 million each year for 10 years. The Department has $1.6 billion in unobligated balances, which are funds that have been appropriated but which there are no plans to spend. In fiscal year 2006, the Department spent $45.9 million on conferences, a 34-percent increase since fiscal year 2000. The inspector general examined just 10 conferences and found that the Department spent an estimated $1.5 million on food and beverages. This included paying $4 per meatball at one lavish dinner and spreading an average of $25 worth of snacks around to each participant at a movie-themed party. It is estimated that the current fiscal year 2008 Commerce, Justice, Science Appropriations bill contains congressional earmarks totaling $587 million and the bill exceeds the President's request by more than $2 billion. Clearly, there is wasteful spending that can be reduced to pay for this program.

Just like American taxpayers, Congress needs to learn to pay for what it spends. This is a reasonable expectation but one that has been ignored by Washington politicians who tend to put off difficult decisions and, as a result, have charged up a $9 trillion debt.

This bill also creates a new Federal program that duplicates an existing Federal Government initiative that seeks to address unsolved civil rights crimes. The Department of Justice and the Civil Rights Division of the Federal Bureau of Investigation are currently working with States and nonprofit groups to pursue unsolved civil rights era crimes that resulted in death.

In February 2006, the FBI began an initiative to identify hate crimes that occurred prior to December 1969, and resulted in death. Since then, the Bureau's 56 field offices began to reexamine their unsolved civil rights cases

and determine which ones might still be viable for prosecution. To date, they have identified nearly 100 case referrals. Furthermore, the U.S. Attorney General and the FBI Director announced a partnership with the NAACP, the Southern Poverty Law Center and the National Urban League to investigate unsolved crimes from the civil rights era.

I am very supportive of this effort and I am also encouraged that these cases are currently being pursued.

On August 2, 2007, I sent a letter to the Attorney General requesting more information about these efforts to ensure that any legislation passed by Congress would assist the Department to meet its goals. I am awaiting a response.

I do believe that solving these crimes is imperative to remedying past injustices and ensuring future justice. These types of crimes should never have been and never again tolerated or ignored.

I also believe that because of the nature of the crime, the time elapsed, and the fact that many witnesses and potential murderers have moved to different States, this is an area of the law that rightly requires Federal assistance.

Consequently, it is my hope that the bill's sponsors will support my efforts to find funding for this worthy program. It is unfortunate that such a well intentioned effort is being held up because Washington politicians refuse to live under the same budget rules that every family in America adheres to. In the meantime, the American people can rest assured knowing that the Department of Justice and the FBI are already conducting the investigations that this bill seeks to address.

PERFORMANCE GOALS FOR THE MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

Mr. KENNEDY. Mr. President, on September 20, 2007, the Senate passed H.R. 3580, the Food and Drug Administration Amendments Act of 2007. Title II of this bill includes the reauthorization of the FDA's medical device user fee program.

Performance goals, existing outside of the statute, accompany the authorization of medical device user fees. These goals represent a realistic projection of what the Food and Drug Administration's Center for Devices and Radiological Health and Center for Biologics Evaluation and Research can accomplish with industry cooperation. The Secretary of Health and Human Services forwarded these goals to the chairmen of the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, in a document entitled ''MDUFA PERFORMANCE GOALS AND PROCEDURES.'' According to Section 201(c) of H.R. 3580, ''the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals . . . in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the CONGRESSIONAL RECORD.''

Today I am submitting for the RECORD this document, which was forwarded to the Committee on Health, Education, Labor and Pensions on September 27, 2007, as well as the letter from Secretary Leavitt that accompanied the transmittal of this document.

I ask unanimous consent this material be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

HEALTH AND HUMAN SERVICES,
Washington, DC, September 27, 2007.

EDWARD M. KENNEDY,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR CHAIRMAN KENNEDY: I want to congratulate you for completing action on the FDA Amendments Act, H.R. 3580. As you know, this bill contains the reauthorization of user fees for drugs and devices as well as other key provisions vital to the Food and Drug Administration. We appreciate your support and hard work on this legislation, the commitment of Members of the Committee in working out these measures, and the support shown by the full Senate.

I am including as enclosures to this letter the two commitment documents for the drug and device user fee programs which outline the agreements between the Agency and the industries with regard to application approval timeframes, issuance of guidances, post market program enhancements, and milestones for other activities to be supported by user fees. These documents cover fiscal years 2008 through 2012 and they represent the commitment of the Department and the FDA to carry out the goals under the mutual agreement with the industries.

Thank you again for successful enactment of the FDA Amendments Act. I look forward to working with you as we proceed with the implementation of this legislation.

Sincerely,

MICHAEL O. LEAVITT,
Secretary.

MDUFA PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures of the FDA Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the medical device user fee program in the Medical Device User Fee Amendments of 2007, are summarized as follows:

I. Review performance goals—Fiscal year 2008 through 2012 as applied to receipt cohorts.

All references to ''days'' mean ''FDA days.''

A. Original premarket approval (PMA), panel-track PMA supplement, and premarket report submissions.

FDA will issue a decision for 60 percent of non-expedited filed submissions within 180 days, and for 90 percent within 295 days.

B. Expedited original PMA and panel-track PMA supplement submissions.

FDA will issue a decision for 50 percent of expedited filed submissions within 180 days, and for 90 percent within 280 days.

C. PMA modules.

FDA will take action on 75 percent of PMA modules within 90 days, and on 90 percent within 120 days.

D. 180-day PMA supplements.

FDA will issue a decision for 85 percent of 180-day PMA supplements within 180 days, and for 95 percent within 210 days.

E. Real-time PMA supplements.

FDA will issue a decision for 80 percent of real-time PMA supplements within 60 days, and for 90 percent within 90 days.

F. 510(k) submissions.

FDA will issue a decision for 90 percent of 510(k)s within 90 days, and for 98 percent within 150 days.

G. Maintenance of current performance.

The agency will, at a minimum, maintain current review performance in review areas such as IDEs and 30-day Notices where specific quantitative goals have not been established.

H. Interactive review.

The agency will continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and sponsors to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and sponsors.

Interactive review is intended to: (a) prevent unnecessary delays in the completion of the review; (b) avoid surprises to the sponsor at the end of the review process; (c) minimize the number of review cycles and extent of review questions conveyed through formal requests for additional information; and (d) ensure timely responses from sponsors.

All forms of communication should be used as ''tools'' to facilitate interactive review. These include, but are not limited to, the following: (a) e-mail; (b) one-on-one telephone calls; (c) telephone conferences; (d) videoconferencing; (e) fax; and (f) face-to-face meetings.

Application of these tools for interactive review should remain flexible, balancing speed and efficiency with the need to ensure supervisory concurrence for significant information requests. In general, e-mail should be the preferred mechanism for informal communication because it creates a clear record of the interaction, with telephone calls used primarily for seeking clarification or answers to very limited questions. Conferencing, either by telephone, video, or face-to-face mechanisms, should be used at key milestones, such as those described below, in the review process.

A cornerstone of interactive review is that communication should occur as needed to facilitate a timely and efficient review process. In particular:

1. There should be regular, informal communication from FDA to seek clarification on issues that can be resolved without substantive review or analysis. When appropriate, FDA will also informally communicate substantive review issues if FDA determines that it will facilitate a timely and efficient review process.

Because all reviewers will be active participants in the interactive review process established under this agreement, it should be a natural outcome that reviewers will share issues with sponsors prior to incorporating them into formal letters.

2. Whenever FDA informally requests additional information, the sponsor and FDA will determine an acceptable timeframe for submission of the information. If the information is not received within the agreed upon